



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,654	04/19/2004	James Nadeau	020187.0208PTUS	2135
63863 7590 05/24/2010 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company (Lerner David Littenberg) 1 Becton Drive , MC 110 Franklin Lakes, NJ 07417-1880				
EXAMINER				
LU, FRANK WEI MIN				
ART UNIT		PAPER NUMBER		
1634				
MAIL DATE		DELIVERY MODE		
05/24/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/826,654

**Applicant(s)**

NADEAU ET AL.

**Examiner**

FRANK W. LU

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14, 16-27, 29, 30, 74 and 78 is/are pending in the application.
- 4a) Of the above claim(s) 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-14, 20-27, 29, 30, 74 and 78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-944)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's response to the office action filed on February 8, 2010 has been entered. The claims pending in this application are claims 1-14, 16-27, 29, 30, 74, and 78 wherein claims 9 and 16-19 have been withdrawn due to the restriction requirement and the election of species mailed on September 28, 2006. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of applicant's amendment filed on February 8, 2010. Claims 1-8, 10-14, 20-27, 29, 30, 74, and 78 will be examined.

### ***Claim Objections***

2. Claim 1 or 74 or 78 is objected to because of the following informalities: (1) "a first single stranded oligonucleotide" in (b) should be "a single stranded first oligonucleotide"; and (2) "a second single stranded oligonucleotide" in (c) should be "a single stranded second oligonucleotide";
3. Claim 23 is objected to because of the following informality: "blocke rligonucleotide" in line 5 should be "blocker oligonucleotide".

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1-8, 10-14, 20-27, 29, 30, 74, and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 is rejected as vague and indefinite in view of step (iii). Since step (iii) does not require that 5' portion of the first or second oligonucleotide in the hybrid is single stranded, if the hybrid is a double stranded nucleic acid with blunt ends at its both 3' and 5' ends, it is unclear why the 3' terminus of the first or second oligonucleotide can be extended and an amplicon can be produced. Please clarify.
7. Claim 1 or 74 is rejected as vague and indefinite in view of step (v) because it is unclear that detection of the amplification product indicates detection of the analyte in where. Please clarify.
8. Claim 22 is rejected as vague and indefinite. Since claim 1 requires to displace the hybridization blocker oligonucleotide before producing the amplicon (see steps (iii) to (v)) and does not require to produce the amplicon in the presence of the hybridization blocker oligonucleotide, it is unclear how the hybridization blocker oligonucleotide can reduce formation of the amplicon by a factor of at least 100-fold as detected in assay relative to amplicon formation without a hybridization blocker oligonucleotide. Please clarify.
9. Claim 23 is rejected as vague and indefinite. Since claim 1 requires to displace the hybridization blocker oligonucleotide before producing the amplicon (see steps (iii) to (v)) and does not require to produce the amplicon in the presence of the hybridization blocker oligonucleotide, it is unclear how the hybridization blocker oligonucleotide can reduce formation of the amplicon by a factor of at least 1000-fold as detected in assay relative to amplicon formation without a hybridization blocker oligonucleotide. Please clarify.
10. Claim 78 is rejected as vague and indefinite in view of step (vi) because it is unclear that detection of the amplification product indicates detection of the analyte in where. Please clarify.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. No claim is allowed.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen, can be reached on (571)272-0731.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frank W Lu /  
Primary Examiner, Art Unit 1634  
May 19, 2010